**Press Release 13 January 2014**

# Interim results (SVR4) from a phase II all-oral combination study of Simeprevir and Samatasvir (IDX719) for the treatment of hepatitis C

**Stockholm, Sweden—Medivir AB (OMX: MVIR),** announces that Idenix Pharmaceuticals, Inc. today released interim data from the ongoing phase II HELIX-1 clinical trial evaluating an all-oral, direct-acting antiviral (DAA) HCV combination regimen of samatasvir (IDX719), Idenix's once-daily pan-genotypic NS5A inhibitor, and simeprevir , a once-daily protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB, and ribavirin.

The combination regimen of the study was well-tolerated. In the treatment-naïve, non-cirrhotic, genotype 1b or 4 HCV-infected patients receiving 50 mg of samatasvir and 150 mg of simeprevir plus ribavirin for 12 weeks, 85 percent (n=17/20) of the patients achieved SVR4 (undetectable HCV RNA four weeks after end of treatment). The 50 mg dose of samatasvir is the selected dose in the ongoing 3-DAA HELIX-2 clinical trial. The HELIX-1 study results are expected to be presented at a scientific meeting in 2014.

**HELIX-1 study design**
The HELIX-1 trial is the first study in HCV-infected patients to commence under a non-exclusive collaboration agreement between Idenix and Janssen which was established in January 2013. The HELIX-1 trial is a phase II 12-week, randomized, parallel group study evaluating the antiviral activity, safety and tolerability of samatasvir and simeprevir in treatment-naïve, non-cirrhotic, genotype 1b or 4 HCV-infected patients.

Patients in part A of the study (n=63) were enrolled in one of three treatment groups receiving 50, 100, or 150 mg samatasvir once-daily for 12 weeks in combination with 150 mg of simeprevir plus a weight-based dose of ribavirin. In part B of the ongoing HELIX-1 study, exploratory cohorts of patients have been added to evaluate the safety and antiviral activity of a 25 mg dose of samatasvir in genotype 1b-infected patients and of a 100 mg dose of samatasvir in genotype 6-infected patients.

A second phase II trial (HELIX-2) was initiated in December 2013 evaluating samatasvir, simeprevir and TMC647055, a once-daily non-nucleoside polymerase inhibitor plus a low-dose ritonavir being developed by Janssen, with and without ribarivin in genotype 1-infected patients who are either treatment-naïve or have previously relapsed after treatment with pegylated interferon and ribavirin.

**For additional information about the HELIX-1 study, please visit www.clinicaltrials.gov**

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 13.15 p.m. CET on 13 January 2014.

**About Simeprevir**
Simeprevir is an NS3/4A protease inhibitor jointly developed by Medivir and Janssen R&D Ireland for the treatment of chronic hepatitis C infection in combination with other antivirals in HCV genotype 1 and 4 infected subjects with compensated liver disease, including cirrhosis.

Simeprevir was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan (trade name Sovriad™) and in the USA (trade name Olysio™) and Canada (trade name Galexos™) in November. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 and genotype 4 chronic hepatitis C. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

*Medivir is a collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C. We are passionate and uncompromising in our mission to develop and commercialize innovative pharmaceuticals that improve people's health and quality of life.*

**About Samatasvir (IDX719)**
Samatasvir is an NS5A inhibitor with low picomolar, pan-genotypic antiviral activity *in vitro*. To date, samatasvir has been safe and well-tolerated after single and multiple doses of up to 150 mg in healthy volunteers up to 14 days duration, and in HCV-infected patients up to 12 weeks duration. There have been no treatment-emergent serious adverse events reported in the program. Samatasvir has demonstrated potent pan-genotypic antiviral activity in HCV-infected patients with mean maximal viral load reductions up to approximately 4.0 $\log_{10}$ IU/mL across HCV genotypes 1-4 in a proof-of-concept, three-day monotherapy study.

**About Medivir**
Medivir is an emerging research-based pharmaceutical company focused on infectious diseases. Medivir has world class expertise in polymerase and protease drug targets and drug development which has resulted in a strong infectious disease R&D portfolio. The Company's key pipeline asset is simeprevir, a novel protease inhibitor for the treatment of hepatitis C that is being developed in collaboration with Janssen R&D Ireland. The company is also working with research and development in other areas, such as bone disorders and neuropathic pain. Medivir has also a broad product portfolio with prescription pharmaceuticals in the Nordics.

**For more information about Medivir AB, please visit the Company's website: www.medivir.com**